DOWD, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Richard T. Frederick, Sr.,	)	
	)	CASE NO. 1:13 CV 1220
Plaintiff,	)	
	)	
v.	)	MEMORANDUM OPINION AND ORDER
	)	
Smith & Nephew, Inc., et al.,	)	
	)	
Defendants.	)	
	)	

The Court previously referred this case to Magistrate Judge Burke for general pretrial supervision, but did not specifically refer the case for preparation of a Report and Recommendation on dispositive motions. Presently before the Court is defendant Smith & Nephew's motion to dismiss plaintiff's third amended complaint. ECF 29. The Court has thoroughly reviewed plaintiff's motion and believes that a prompt ruling on this motion is in the interest of efficiency and judicial economy. For the reasons that follow, defendant's motion to dismiss plaintiff's third amended complaint is DENIED.

A. Background

This removed diversity jurisdiction case involves a claim by plaintiff for injuries allegedly sustained as a consequence of a hip prosthesis that was implanted in plaintiff's hip in 2009. Plaintiff alleged in his original complaint that the hip prosthesis was designed, manufactured, marketed and sold by defendant Smith & Nephew, but a specific model was not identified. The Court conducted a case management conference on August 5, 2013, and opened discovery to be completed by November 15, 2013.

Another conference in this case was conducted on November 25, 2013. Shortly before the status conference, plaintiff filed a third amended complaint.

Plaintiff's third amended complaint claims that he was injured by a metal-on-metal femoral head prosthesis used to replace his right hip in 2009, and that the prosthesis used in his hip replacement was manufactured, marketed and sold by defendant Smith & Nephew. Plaintiff's complaint asserts that the Smith & Nephew device is known as the Birmingham Hip Resurfacing System (BHR).[1] The third amended complaint alleges various state law claims, including claims that the device was defectively designed, that defendant failed to adequately warn of the design defect of which it was aware, and that defendant breached its express and implied warranties that the device was safe and reliable, all of which was the proximate cause of plaintiff's injuries.

Although discovery had been open for three months, the Court learned at the status conference, only two days before defendant's motion to dismiss was filed, that the defendant had yet to examine and identify the actual hip prosthesis and any components used in plaintiff's surgery, which according to plaintiff's counsel, is presently in the custody of Hillcrest Hospital. Further, plaintiff's counsel provided defendant's counsel and the Court with a letter from Dr. Anouchi at University Hospitals. Dr. Anouchi opines in his letter that, to a reasonable degree of medical certainty, a Smith & Nephew product was used in plaintiff's hip replacement and that

[1] It is unclear from the complaint whether the BHR "system" referred to in the complaint includes all of the component parts used in plaintiff's hip replacement surgery, because the complaint also refers to a "femoral head" and "prosthetic devices."

product is responsible for plaintiff's injuries.[2] However, Dr. Anouchi's letter does not identify the Smith & Nephew product or products used in plaintiff's original surgery.

B. Defendant's Motion to Dismiss

Defendant Smith & Nephew makes two legal arguments in support of its motion to dismiss. First, defendant contends that plaintiff's third amended complaint is preempted by the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act. *See* Medical Device Amendments of 1976, § 2(a), 21 U.S.C.A. § 360k(a). Pursuant to § 360k(a), state-law causes of action are expressly preempted to the extent they impose requirements different from, or in addition to, the requirements of federal law. *Riegel v. Medtronic, Inc.*, 522 U.S. 312 (2008).

Defendant's second argument in support of its motion is that plaintiff's claims are inadequately pled with the specificity required by Rule 8(a) of the Federal Rules of Civil Procedure and by the controlling Supreme Court case law of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

C. Law and Analysis

1. *Preemption determination is premature*

Defendant argues that plaintiff's claims are preempted by the MDA because the state laws under which plaintiff's claims are brought impose different or additional requirements on

[2] Dr. Anouchi is identified in plaintiff's third amended complaint as the physician who conducted the testing and diagnosed the injury which plaintiff claims was caused by defendant's hip replacement prosthesis. Dr. Anouchi is not the physician who performed plaintiff's hip replacement in 2009.

the device at issue than was imposed by the FDA. However, the preemption provision of the MDA contained in 21 U.S.C. § 360k(a) "was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Hawkins v. Medtronic*, 909 F.Supp.2d 901, 904 (S.D. Ohio 2012) (quoting *Medtronic v. Lohr*, 518 U.S. 470, 491 (1966)). State laws regarding medical devices are preempted only when the FDA has established specific regulations or requirements applicable to a particular device, and the state law imposes different or additional requirements on the device. *Hawkins v. Medtronic*, 909 F.Supp.2d at 904-05 (S.D. Ohio 2012) (quoting *Riegel v. Medtronic, Inc.*, 522 U.S. at 322).

Claims that a defendant manufacturer is liable under state law for injuries allegedly caused by a medical device, even though the manufacturer complied with the FDA requirements for pre-market approval (PMA) of a device, are preempted by federal law to the extent that the state law imposes requirements different from or in addition to the FDA requirements. However, claims premised on a violation of FDA regulations or requirements are "parallel" claims and do not impose requirements that are different from or in addition to federal requirements, and may not be preempted by the MDA. *Hawkins v. Medtronic*, 909 F.Supp.2d at 904 (S.D. Ohio 2012) (quoting *Riegel v. Medtronic, Inc.*, 522 U.S. at 330).

The first step in a MDA preemption analysis is to determine whether the federal government has established requirements or regulations applicable to the medical device(s) in question. *Hawkins v. Medtronic*, 909 F.Supp.2d at 904-05 (S.D. Ohio 2012) (quoting *Riegel v. Medtronic, Inc.*, 522 U.S. at 322). FDA pre-market approval of a medical device automatically satisfies the first condition of the preemption test. *Hawkins v. Medtronic*, 909 F.Supp.2d at 905

(S.D. Ohio 2012) (quoting *Riegel v. Medtronic, Inc.*, 522 U.S. at 322-23). Attached to defendant's motion to dismiss is a PMA letter from the FDA for the BHR device, which defendant argues establishes as a matter of law that plaintiff's claims are preempted by the MDA.

However, discovery is not complete and the defendant conceded to the Court that it has not examined the device and any component parts utilized in plaintiff's original surgery. Dr. Anouchi's letter does not specifically identify the Smith & Nephew device and any component parts used in plaintiff's surgery. Devices and component parts for which the FDA has not established regulations or requirements are not preempted by the MDA. It is premature to conclude at this stage of the lawsuit that the PMA letter issued by the FDA for the BHR preempts all of plaintiff's claims.

Further, the specific details, extent and scope of the federal requirements and/or regulations imposed by the PMA for the BHR are not yet fully developed in the record, and some areas may be specifically excluded from regulation.[3] The details of the PMA's requirements and conditions for the BHR are relevant to defendant's preemption argument because not all state laws are preempted by the MDA, only state requirements that are additional to or different from federal requirements. In addition, the PMA for the BHR attached by defendant to its motion to dismiss was issued in 2006. The document on its face provides for

[3] For example, page 3 of the PMA attached to defendant's motion to dismiss states as follows: "CDRH [The Center for Devices and Radiological Health] does not evaluate information related to contract liability warranties, however you should be aware that such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws." ECF 29-1, Page ID # 134.

revision as appropriate in light of the various reporting requirements imposed upon defendant by the PMA. Any subsequent revisions to federal requirements and regulations which defendant claims preempts plaintiff's claims are also relevant to a final preemption determination.

Until the device and all component parts used in plaintiff's original surgery are specifically identified, and until all federal requirements applicable to those devices and components are fully discovered, it is premature to conclude that plaintiff's claims are subject to preemption under the MDA. Accordingly, defendant's motion to dismiss on the grounds that plaintiff's claims are preempted is DENIED. However the Court notes that, if following the completion of discovery, it appears that the device and any component parts are entirely regulated by the FDA, and that plaintiff cannot sustain a claim under state requirements that parallel federal requirements, then defendant is free to file a motion for summary judgment in accordance with the Court's case management plan.

2. *Plaintiff's complaint satisfies Twombly/Iqbal pleading requirements*

Defendant's second argument in support of its motion to dismiss is that plaintiff has failed to plead sufficient facts to state a claim for relief that is plausible on its face under the *Twombly/Iqbal* pleading standard, and the third amended complaint should be dismissed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

Rule 8 of the Federal Rules of Civil Procedure requires that the complaint contain a short and plain statement showing that the plaintiff is entitled to relief. In order to overcome a motion to dismiss, plaintiff's complaint must contain sufficient factual content, not mere conclusory allegations, to raise a plausible inference of wrongdoing. *16630 Southfield Limited Partnership*

v. Flagstar Bank, 727 F.3d 502, 504 (6th Cir. 2013) (citations omitted).

Defendant bears the burden of establishing that plaintiff has failed to state a claim for relief. *Huffman v. Electrolux North America, Inc.*, --F.Supp.2d--, 2013 WL 4428803 (N.D. Ohio) (citing *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007)). For purposes of defendant's motion to dismiss, the Court must view the complaint in a light most favorable to the plaintiff and accept all well-pleaded factual allegations as true. *Marcum v. DePuy Orthopedics, Inc.*, 2013 WL 1867010 (S.D. Ohio). However, the Court is not required to accept as true legal conclusions that are not supported by factual allegations. *Horn v. Husqvarna Consumer Outdoor Products N.A., Inc.*, 2013 WL 693119 at * 1 (S.D. Ohio 2013) (citing *Ashcroft v. Iqbal*, 556 U.S. 622, 677 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007))). The Rule 12(b)(6) standard requires more than a bare assertion of legal conclusions to survive a motion to dismiss. However, the complaint need not contain detailed factual allegations, but must contain factual allegations sufficient to give the defendant fair notice of the claim and the grounds upon which it rests. *Horn v. Husqvarna Consumer Outdoor Products N.A., Inc.*, 2013 WL 693119 at * 1 (citations omitted).

With respect to plaintiff's allegation of defective design in Count 1, plaintiff's claims are not mere formulaic legal conclusions and "unadorned, the-defendant-unlawfully-harmed-me," accusations. Plaintiff alleges that defendant's product caused a tumor and soft tissue destruction around his hip joint with severe metallosis due to metal-on-metal hip replacement. These factual allegations state a plausible claim for relief sufficient to survive defendant's Rule 12(b)(6) motion to dismiss.

Similarly with respect to plaintiff's claim of inadequate warning/instruction in Count 2, plaintiff alleges that defendant's warning was inadequate due to failure to warn of the devices "propensity to embed foreign matter causing metallosis to the tissues surrounding the area of the prosthesis," and failure to warn of recalls issued by manufacturers of similar products and designs. These allegations contain sufficient factual detail to place defendant on notice of a plausible claim.

As to plaintiff's claim in Count 3 regarding failure of the device to conform to representations and breach of express and implied warranties, plaintiff specifies in his complaint the product literature at issue: sales literature, warranties, sales representations and pictures. These factual allegations are specific enough to put defendant on notice of the literature and content at issue, and are sufficient at the pleadings stage to survive defendant's motion to dismiss.

Lastly, defendant contends that Count 4 should be dismissed because plaintiff cannot recover punitive damages for a failure to recall. However, plaintiff's punitive damages claim alleges not only a failure to recall but that defendant's conduct, as alleged in the factual allegations and Counts 1-4, constitutes misconduct that manifests a flagrant disregard for the safety of persons who might be harmed by the product in question. The nature of the conduct in question that plaintiff alleges supports a punitive damages claim is sufficiently detailed throughout the complaint to put defendant on notice of a plausible claim and withstand defendant's motion to dismiss.

D. Conclusion

For the reasons contained herein, defendant's motion to dismiss on the grounds of preemption is DENIED. However, defendant may reassert the preemption issue at a later time as detailed, *supra.*

Further for the reasons contained herein, defendant's motion to dismiss on the grounds that plaintiff's third amended complaint fails to satisfy the required pleading standard of Rule 8 and *Twombly* and *Iqbal* is DENIED. Plaintiff's third amended complaint contains sufficient factual detail to place defendant on notice of a plausible claim.

This case remains before Magistrate Judge Burke for general pretrial supervision as previously assigned.

IT IS SO ORDERED.

December 4, 2013
Date

s/ David D. Dowd, Jr.
David D. Dowd, Jr.
U.S. District Judge